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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/712,629	11/13/2003	Kotikanyadanam Sreekrishna	9423	5723

27752 7590 01/27/2006

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EXAMINER

DUNSTON, JENNIFER ANN

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 01/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/712,629	Applicant(s) SREEKRISHNA ET AL.	
	Examiner Jennifer Dunston	Art Unit 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 16 November 2004 and 24 October 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) 3-8 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 2 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>3/19/04, 8/10/05</u>  | 6) <input checked="" type="checkbox"/> Other: <u>sequence alignments</u>    |

Art Unit: 1636

## DETAILED ACTION

### *Election/Restrictions*

Applicant's election without traverse of Group I and SEQ ID NO: 2 (*Homo sapiens* Ubiquitous Receptor) in the reply filed on 11/16/2004 is acknowledged.

Claims 3-8 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Election was made **without** traverse in the reply filed on 11/16/2004.

### *Information Disclosure Statement*

Receipt of information disclosure statements, filed on 3/19/2004 and 8/10/2005, is acknowledged. The signed and initialed PTO 1449s have been mailed with this action.

### *Specification*

The amendment filed 10/24/2005 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows:

The specification has been amended to define "truncated hairless protein (HRT)" as the sequence provided as SEQ ID NO: 17 (page 5, line 34 to page 6, line 10). Further, the specification has been amended to indicate that SEQ ID NO: 18 is the nucleic acid sequence encoding amino acids 490 to 1182 of mouse hairless protein (page 7, lines 7-35). The sequence

Art Unit: 1636

listing has been amended to include new sequences, SEQ ID NOS: 17 and 18, which were not present in the original sequence listing.

A review of the sequence listing, filed 10/24/2005, indicates that SEQ ID NO: 17 is a nucleic acid sequence, and SEQ ID NO: 18 is an amino acid sequence. Thus, the specification should indicate that the truncated hairless protein is provided in SEQ ID NO: 18, rather than SEQ ID NO: 17. The specification indicates that the truncated hairless protein is amino acid residues 490-1182 of the C-terminal portion of mouse hairless (HR) protein (e.g. page 5, line 34 to page 6, line 10). This sequence should be contained in SEQ ID NO: 18. However, a search of the commercial sequence databases using SEQ ID NO: 18 did not identify a single sequence of 100% identity to SEQ ID NO: 18. For example, SEQ ID NO: 18 is 99.4% identical to amino acids 490-1182 of I48378, which is 100% identical to GenBank Accession No. CAA83587 (see the attached sequence alignments for I48378 and the GenBank entry for CAA83587). There are three mismatches between the protein of instant SEQ ID NO: 18 and the protein of I48378. For clarity, a second alignment comparing the protein encoded by Z32675 and the protein of I48378 is provided. This alignment demonstrates that the proteins of I48378 and the protein encoded by Z32675 are 100% identical. An inspection of the sequences provided by Applicants and the sequences known in the art as mouse hairless protein indicates that the sequence provided by Applicants is not amino acid residues 490-1182 of mouse hairless protein.

The specification provides support for the amino acid sequence of mouse hairless protein encoded by GenBank Accession No. Z32675 (e.g. page 7, lines 7-35). However, the sequence provided in the sequence listing is not identical to this sequence. Thus, the amendment is a departure from the specification as originally filed.

Art Unit: 1636

Applicant is required to cancel the new matter in the reply to this Office Action.

*Claim Objections*

Claims 1 and 2 are objected to because of the following informalities: the claims read on non-elected embodiments.

*Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 2 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 2 are vague and indefinite in that the metes and bounds of the term "mouse HRt protein" are unclear. The term is unclear in that the specification defines "truncated hairless protein (HRt) as the sequence provided as SEQ ID NO: 17 (page 5, line 34 to page 6, line 10). However, a review of the sequence listing indicates that SEQ ID NO: 17 is a nucleic acid sequence, and SEQ ID NO: 18 is an amino acid sequence. For the purposes of examination the term "mouse HRt protein" has been interpreted as the amino acid sequence provided in SEQ ID NO: 18.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it

Art Unit: 1636

pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 2 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new matter rejection.**

The claims are drawn to a composition comprising a mouse HRt protein. The specification defines "truncated hairless protein (HRt)" as the sequence provided as SEQ ID NO: 17 (page 5, line 34 to page 6, line 10). A review of the sequence listing, filed 10/24/2005, indicates that SEQ ID NO: 17 is a nucleic acid sequence, and SEQ ID NO: 18 is an amino acid sequence. Thus, the specification should indicate that the truncated hairless protein is provided in SEQ ID NO: 18, rather than SEQ ID NO: 17. Therefore, the claims have been interpreted as being drawn to a composition comprising a protein of SEQ ID NO: 18.

The specification indicates that the truncated hairless protein is amino acid residues 490-1182 of the C-terminal portion of mouse hairless (HR) protein (e.g. page 5, line 34 to page 6, line 10). This sequence should be contained in SEQ ID NO: 18. However, a search of the commercial sequence databases using SEQ ID NO: 18 did not identify a single sequence of 100% identity to SEQ ID NO: 18. For example, SEQ ID NO: 18 is 99.4% identical to amino acids 490-1182 of I48378, which is 100% identical to GenBank Accession No. CAA83587 (see the attached sequence alignments for I48378 and the GenBank entry for CAA83587). There are three mismatches between the protein of instant SEQ ID NO: 18 and the protein of I48378. For clarity, a second alignment comparing the protein encoded by Z32675 and the protein of I48378

Art Unit: 1636

is provided. This alignment demonstrates that the proteins of I48378 and the protein encoded by Z32675 are 100% identical. An inspection of the sequences provided by Applicants and the sequences known in the art as mouse hairless protein indicates that the sequence provided by Applicants is not amino acid residues 490-1182 of mouse hairless protein.

The specification provides support for the amino acid sequence of mouse hairless protein encoded by GenBank Accession No. Z32675 (e.g. page 7, lines 7-35). However, the sequence provided in the sequence listing is not identical to this sequence. Thus, the amendment is a departure from the specification as originally filed.

#### *.. Conclusion*

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Dunston whose telephone number is 571-272-2916. The examiner can normally be reached on M-F, 9 am to 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached at 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR, <http://pair-direct.uspto.gov>) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business

Art Unit: 1636

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Jennifer Dunston  
Examiner  
Art Unit 1636

jad

**CELIAN QIAN**  
**PATENT EXAMINER**

